

REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments made above and the remarks that follow.

Applicant acknowledges and appreciates the indicated allowability of claims 10-12 if rewritten in independent form to include the limitations of the base claim and any intervening claims. It is respectfully submitted that the remaining claims also are allowable, as discussed below.

Medical treatment frequently requires the use of intravenous (IV) lines to inject or remove materials from a patient. In many cases, multiple lines must be used simultaneously. In these instances, and especially in a rushed and chaotic environment, accidental mixing of IV lines can occur, with potentially deadly results for the patient.

The present invention provides a simple, inexpensive and effective solution to this problem. The invention is an IV line holder and organizer comprising a thin flat piece of material, preferably paperboard or other suitable material having sufficient rigidity and flexibility to function as intended, and provided with at least one foldable wing having a plurality of openings therethrough, with slits leading to the openings and through which lengths of IV tubing can be inserted for engagement in the openings to hold the IV lines separated and organized. The holder has a flat portion on which indicia can be placed in registry with the IV lines held thereby, to provide a quick and reliable visual indication of the proper placement and connection of the IV lines. In a preferred embodiment, two wings are provided on opposite sides of a flat central portion, and the wings are folded downwardly so that the flat central portion is disposed above the IV lines to ensure that the indicia placed on the flat central portion is not obscured or rendered difficult to read by the IV lines.

In the Office Action of October 7, 2004, claims 1-4, 9 and 13 were rejected under 35 USC 103(a) as unpatentable over Kurtz (3286713) modified by Wilder (4606735). Kurtz was said to teach a holder with a central flat portion, a marginal edge portion having an outer end edge, an opening formed through the marginal edge portion, and a slit leading through the end edge to the opening, through which a length of IV tubing could be inserted. Kurtz was said to

have opposite marginal edge portions that are bendable to define a pair of opposed wings having aligned openings. It was recognized that Kurtz does not have a plurality of openings, and Wilder was cited for its teaching of a plurality of openings, with the position being taken that it would have been obvious to modify Kurtz to provide it with a plurality of openings in view of Wilder.

5 Claims 5-8 and 14-15 were rejected under 35 USC 103(a) as unpatentable over Kurtz in view of Wilder as in rejecting claim 1, further modified by Gordon (5573111). It was recognized that Kurtz modified by Wilder does not teach a holder made of paperboard, or the series of short radial cuts around the edges of the openings. The position was taken that it would be obvious in view of Gordon to further modify the combination of Kurtz and Wilder by making the Kurtz
10 holder of paperboard, and providing short radial cuts around the opening.

It is respectfully submitted that Kurtz, Wilder and Gordon do not teach the present invention, whether these patents are considered individually or in combination. There simply is no suggestion in any of these references of the presently claimed invention.

Kurtz is directed to a surgical dressing designed to surround a tubular object that leaves
15 the body, and particularly to a dressing that protects the entire skin area immediately surrounding the opening through which the tubular device leaves the body. The sheet 4 in Kurtz is made of a suitable absorbent material such as gauze, thin plastic foam sponge, wet strength non-woven fabric, etc., and obviously is intended to have the physical characteristics of a dressing. It does not relate to nor would it function as an IV line holder that holds a plurality of IV lines in
20 separated and organized relationship. It is a dressing material, and is designed to be placed on a tube so that the tube holds the dressing in place, rather than something that holds a plurality of lines in separated and organized relationship. Because of its intended use, it is not apparent that multiple openings would have any function, or how multiple openings would even work to hold the dressing or dressings in place. Moreover, because of its intended use there is no provision
25 for placement of indicia, nor would there be any reason for providing such a structure and function. Further, Kurtz does not suggest a holder having a central portion and opposite bendable wings. In Kurtz, the two panel portions on opposite sides of the fold line 7 appear to be folded into contiguous, parallel relationship with one another (see figure 4).

Wilder is a medical tubing holder having a central portion and a pair of opposite bendable wings with plural openings formed therethrough. However, the Wilder device is designed and intended to hold a single IV line in place so that it does not become dislodged. Figure 1 shows the preferred embodiment, wherein a single opening is provided in each wing, and figure 5 shows an alternate embodiment wherein multiple openings are provided. However, both embodiments are intended to hold a single line. Obviously, with a single line, there is no need for indicia, nor is there any suggestion in Wilder of holding a plurality of separate lines in separated and organized relationship to avoid accidental mixing and mis-connection of the lines. Simply placing a plurality of openings in Kurtz in view of the plural openings found in Wilder would not produce the claimed invention. Moreover, there is no suggestion or teaching in either Wilder or Kurtz of making this proposed modification.

Gordon is directed to a paperboard bottle carrier and is in a non-analogous art. Although it does show a device made of paperboard, and short radial slits around the edges of the openings, it is not likely that someone having ordinary skill in the art would look to the bottle carrier art for a solution to problems found in the medical devices art. There simply is no suggestion in this patent of modifying either Wilder or Kurtz. Even if Kurtz were modified in view of Gordon to make the Kurtz device of paperboard, the intended use of Kurtz as a dressing likely would be defeated.

In determining the differences between the prior art and the claims, the question under 35 USC 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.* 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983). Distilling an invention down to the “gist” or “thrust” of an invention disregards the requirement of analyzing the subject matter “as a whole”. *W.L. Gore & Associates, Inc. v. Garlock, Inc.* 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

A patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the “subject matter as a whole” which should always be considered in determining the obviousness of an invention under 35 USC 103. *In re Spinnoble*, 405 F.2d 578, 160 USPQ 237 (CCPA 1969)

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success.

5 Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)

10 If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, or require a substantial reconstruction and redesign of the elements shown in the primary reference, then the teachings of the references are
15 not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 122 USPQ 349 (CCPA 1959).

In view of the above, it is respectfully submitted that the rejection of the claims as obvious over Kurtz modified in view of Wilder and Gordon is improper and should be withdrawn and the claims allowed.

Respectfully submitted,

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